



PTO/SB/08A (08-03)

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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Complete if Known

Application Number	10/780,948
Filing Date	February 17, 2004
First Named Inventor	Mark D. Erion
Art Unit	1614
Examiner Name	Patrick T. Lewis
Attorney Docket Number	MET-016XDT

Sheet

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of

2

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
PL	U1	US-6,756,360	06-29-2004	Erion <i>et al.</i>	All
	U2	US-6,919,322	07-19-2005	Bookser <i>et al.</i>	All
	U3	US-6,965,033	11-15-2005	Jiang <i>et al.</i>	All
	U4	US-6,967,193	11-22-2005	Dang <i>et al.</i>	All
	U5	US-6,284,748	09-04-2001	Dang <i>et al.</i>	All
	U6	US-6,489,476	12-03-2002	Dang <i>et al.</i>	All
	U7	US-6,110,903	08-29-2000	Kasibhatla <i>et al.</i>	All
PL	U8	US-6,399,782	06-04-2002	Kasibhatla <i>et al.</i>	All
	U9	US-2005/0176684	08-11-2005	Bookser <i>et al.</i>	All

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				
PL	F1	WO 06/023515 CD-ROM	03-02-2006	Metabasis Therapeutics	All	
	F2	WO 00/14095 CD-ROM	03-16-2000	Metabasis Therapeutics	All	
	F3	WO 00/38666 CD-ROM	07-06-2000	Metabasis Therapeutics	All	
	F4	WO 01/47935 CD-ROM	07-05-2001	Metabasis Therapeutics	All	
	F5	WO 01/66553 CD-ROM	09-13-2001	Metabasis Therapeutics	All	

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PL	U10	US-2003/0073728	04-17-2003	van Poelje <i>et al.</i>	All
PL	U11	US-2005/0004077	01-06-2005	Jiang <i>et al.</i>	All
PL	U12	US-2004/0058892	03-25-2004	Dang <i>et al.</i>	All
	U13	US-			
	U14	US-			
	U15	US-			
	U16	US-			
	U17	US-			
	U18	US-			

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PL	F6	WO 02/03978 CD-ROM	01-17-2002	Metabasis Therapeutics	All	
	F7					
	F8					
	F9					
	F10					
	F11					
	F12					

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			First Named Inventor	Mark D. Erion	
			Art Unit	1614	
			Examiner Name		
Sheet	1	of	6	Attorney Docket Number	MET-016XDT

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PK	U1	US-4,278,791	07-14-1981	Botta et al.	All
	U2	US-5,342,850	08-30-1994	Ohnota et al.	All
	U3	US-6,147,101	11-14-2000	Maeda et al.	All
	U4	US-5,728,704	03-17-1998	Mylari et al.	All
	U5	US-6,054,587	04-25-2000	Reddy et al.	All
	U6	US-6,294,672	09-25-2001	Reddy et al.	All
	U7	US-6,312,662	11-06-2001	Erion et al.	All
	U8	US-			
	U9	US-			

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PK	F1	EP 0354322	06-16-1989	American Cyanamid Company	All	
	F2	WO 99/47549	09-23-1999	Ontogen Corp.	All	
	F3	WO 99/45016	09-10-1999	Metabasis Therapeutics Inc.	All	
	F4	WO 00/27401	05-18-2000	Warner-Lambert Co.	All	
	F5	WO 01/52825	07-26-2001	Novartis AG	All	
	F6	WO 90/08155	07-26-1990	Board of Regents- University of Texas	All	
	F7	WO 90/10636	09-20-1990	Board of Regents- University of Texas	All	

Examiner Signature		Date Considered	7-22-07
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R	R1	AZEN, S.P., et al., "TRIPOD (TROglitazone In the Prevention of Diabetes): A Randomized, Placebo-Controlled Trial of Troglitazone in Women with Prior Gestational Diabetes Mellitus," <i>Controlled Clinical Trials</i> , Vol. 19, Issue 2, Pages 217-231, Elsevier B.V. (April 1998).	
	R2	CHIASSEON, J.-L., et al., "Acarbose for the prevention of Type 2 diabetes, hypertension and cardiovascular disease in subjects with impaired glucose tolerance: facts and interpretations concerning the critical analysis of the STOP-NIDDM Trial data," <i>Diabetologia</i> , 47: 969-975, Springer-Verlag (2004).	
	R3	DELORME, S., et al., "Acarbose in the prevention of cardiovascular disease in subjects with impaired glucose tolerance and type 2 diabetes mellitus," <i>Current Opinion in Pharmacology</i> , 5:184-189, Elsevier (2005).	
	R4	DICKSON, J.K. et al., "Orally Active Squalene Synthase Inhibitors: Bis((acyloxy)alkyl) Prodrugs of the α -Phosphonosulfonic Acid Moiety" <i>J. Med. Chem.</i> 39: 661-664 American Chemical Society (1996).	
	R5	EGRON, D. et al., "Synthesis and Anti-HIV Activity of Some S-Acyl-2-Thioethyl (Sate) Phosphoramidate Derivatives of 3'-Azido-2',3'Dideoxythymidine" <i>Nucleosides & Nucleotides</i> 18(4&5): 981-982 Marcel Dekker, Inc. (1999).	
	R6	ERION, M.D. et al., "Computer-Assisted Scanning of Ligand Interactions: Analysis of the Fructose 1,6-Bisphosphatase-AMP Complex Using Free Energy Calculations" <i>J. Am. Chem. Soc.</i> 122: 6114-6115 American Chemical Society (2000).	
	R7	ERION, M.D. and REDDY, M.R. "Ligand Interaction Scanning Using Free Energy Calculations" <i>Free Energy Calculations in Rational Drug Design</i> , Chapter 11, 225-241 Springer-Verlag (2001).	
	R8	ERION, M.D. et al., "MB06322 (CS-917): A Potent and Selective Inhibitor of Fructose 1,6-Bisphosphatase for Controlling Gluconeogenesis in Type 2 Diabetes" <i>PNAS</i> 102(22): 7970-7975 (May 31, 2005).	
	R9	FISHER, J.S. et al., "Glucose transport rate and glycogen synthase activity both limit skeletal muscle glycogen accumulation," <i>The American Journal of Physiology Endocrinol. Metab.</i> , Vol. 282, pp. E1214-E1221, American Physiological Society (June 2002).	
R	R10	FUJIWARA, T. et al., "Suppression of Hepatic Gluconeogenesis in Long-Term Troglitazone Treated Diabetic KK and C57BL/KsJ-db/db Mice" <i>Metabolism</i> 44(4): 486-490 (April 1995).	

Examiner Signature	<i>Patricia Law</i>	Date Considered	7-22-07
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Sheet	3	of	6	Attorney Docket Number	MET-016XDT

NON PATENT LITERATURE DOCUMENTS			
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PC	R11	GIDH-JAIN, M. <i>et al.</i> , "The Allosteric Site of Human Liver Fructose-1,6-Bisphosphatase" <i>Journal of Biological Chemistry</i> , 269(44): 27732-27738 The American Society for Biochemistry and Molecular Biology, Inc. (1994).	
	R12	HOLMAN, R.R. "Assessing the potential for α -glucosidase inhibitors in prediabetic states," <i>Diabetes Research and Clinical Practice</i> , Vol. 40, Supp. 1, Pages S21-S25, Elsevier Ireland Ltd. (July 1998).	
	R13	HULLEY, S. <i>et al.</i> , "Randomized Trial of Estrogen Plus Progestin for Secondary Prevention of Coronary Heart Disease in Postmenopausal Women," <i>J. of Am. Medical Assoc.</i> , Vol. 280, No. 7, pp. 605-613 (August 19, 1998).	
	R14	INZUCCHI, S.E. <i>et al.</i> , "Efficacy and Metabolic Effects of Metformin and Troglitazone in Type II Diabetes Mellitus" <i>N.E. Journal of Medicine</i> 338(13): 867-872 Massachusetts Medical Society (March 26, 1998).	
	R15	LINK, J.T. <i>et al.</i> , "Pharmacological regulation of hepatic glucose production," <i>Curr. Opin. Investig. Drugs</i> , 4(4):421-429 (April 2003).	
	R16	MAGGS, D.G. <i>et al.</i> , "Metabolic Effects of Troglitazone Monotherapy in Type 2 Diabetes Mellitus" <i>Annals of Internal Medicine</i> 128(3): 176-185 American College of Physicians (February 1, 1998).	
	R17	OKUNO, A. <i>et al.</i> , "CS-917, a Fructose 1,6-Bisphosphatase (FBPase) Inhibitor, Suppresses Gluconeogenesis In Vitro and In Vivo by a Different Mechanism than Metformin" poster presented at The American Diabetes Association 66 th Scientific Session, Washington, DC (June 2006).	
	R18	PICKAVANCE, L. <i>et al.</i> , "The Development of Overt Diabetes in Young Zucker Diabetic Fatty (ZDF) Rats and the Effects of Chronic MCC-555 Treatment" <i>British Journal of Pharmacology</i> , 125: 767-770 Stockton Press (1998).	
✓	R19	POTTER, S.C. <i>et al.</i> , "Effect of MB06322, a Potent and Selective Inhibitor of Fructose 1,6-Bisphosphatase, on Gluconeogenesis in the ZDF Rat as Assessed by the Deuterated Water Technique" <i>DIAEAZ</i> 52(2): A364, Journal of the American Diabetes Association Abstract No. 1516-P, American Diabetes Association (June 2004).	
PL	R20	POTTER, S.C. "Evidence Implicating Gluconeogenesis Inhibition as the Mechanism by Which MB06322 Lowers Blood Glucose In Vivo" <i>DIAEAZ</i> 52(2): A364, Journal of the American Diabetes Association Abstract No. 1517-P, American Diabetes Association (June 2004).	

Examiner Signature	<i>Patricia Lee</i>	Date Considered	7-22-07
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PK	R21	PRISANT, L.M., "Preventing Type II Diabetes Mellitus," <i>J. Clin. Pharmacol.</i> , 44:406-413, American College of Clinical Pharmacology (2004).	
1	R22	REDDY, M.R. and ERION, M.D. "Computer Aided Drug Design Strategies Used in the Discovery of Fructose 1,6-Bisphosphatase Inhibitors" <i>Current Pharmaceutical Design</i> 11: 283-294 Bentham Science Publishers Ltd. (2005).	
	R23	REDDY, K.R. <i>et al.</i> , "Discovery of 2-Aminopyridine Inhibitors of FBPase" abstract for the 230 th National American Chemical Society (ACS) Meeting, Washington, DC, Aug./Sept. 2005, ACSMEDI Program and Abstract Book Archives, pp. 197-198, MEDI 323, obtained from http://oasys.acs.org/acs/230nm/medi/staff/separates.cgi 8/8/2005.	
	R24	REDDY, M.R. and ERION, M.D. "Fructose 1,6-Bisphosphatase: Use of Free Energy Calculations in the Design and Optimization of AMP Mimetics" <i>Free Energy Calculations in Rational Drug Design</i> , Chapter 14, 285-297 Springer-Verlag (2001).	
	R25	SATHYAPRAKASH, R. <i>et al.</i> , "Preventing Diabetes by Treating Aspects of the Metabolic Syndrome," <i>Current Diabetes Reports</i> , 2:416-422, Current Science Inc. (2002).	
	R26	SREENAN, S. <i>et al.</i> , "Prevention of Hyperglycemia in the Zucker Diabetic Fatty Rat by Treatment with Metformin or Troglitazone" <i>Am. J. Physiol.</i> 271 (<i>Endocrinol. Metab.</i> 34): E742-E747 American Physiological Society (1996).	
	R27	SRIVASTVA, D.N. and FARQUHAR, D. "Bioreversible Phosphate Protective Groups: Synthesis and Stability of Model Acyloxymethyl Phosphates" <i>Bioorganic Chemistry</i> 12: 118-129 Academic Press, Inc. (1984).	
	R28	TORRES, T. <i>et al.</i> , "Inhibition of glycogen phosphorylase suppresses basal and glucagon-induced glucose production and increases glucose uptake in the liver of conscious dogs" (Integrated Physiology—Liver 1484-P), <i>Diabetes</i> , Vol. 52 i6, p. A343, American Diabetes Association (June 2003).	
✓	R29	TRISCARI, J. <i>et al.</i> , "Multiple Ascending Doses of CS-917, a Novel Fructose 1,6-Bisphosphatase (FBPase) Inhibitor, in Subjects with Type 2 Diabetes Treated for 14 Days" poster presented at The American Diabetes Association 66 th Scientific Session, Washington, DC (June 2006).	
PK	R30	TURNBULL, A. <i>et al.</i> , "Pharmacological inhibition of glycogen phosphorylase (GP) lowers plasma glucose in rat models of type 2 diabetes. (Integrated Physiology—Liver 1485-P)," <i>Diabetes</i> , Vol. 52 i6, American Diabetes Association (June 2003).	

Examiner Signature	<i>Ratish Sen</i>	Date Considered	7-22-07
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PC	R31	TURNER, R.C. <i>et al.</i> , "U.K. Prospective Diabetes Study 16: Overview of 6 Years' Therapy of Type II Diabetes, a Progressive Disease. (U.K. Prospective Diabetes Study Group)" <i>Diabetes</i> 44(11): 1249(10) American Diabetes Association (Nov. 1995).	
	R32	VAN POELJE, P.D. <i>et al.</i> , "Characterization of the Mechanism of Action and Antidiabetic Activity of MB06322, a Potent and Selective Inhibitor of Fructose 1,6-Bisphosphatase" <i>DIAEAZ</i> 52(2): A366, Journal of the American Diabetes Association Abstract No. 1523-P, American Diabetes Association (June 2004).	
	R33	VAN POELJE, P.D. <i>et al.</i> , "Comparative Metabolic Effects of a Novel Fructose 1,6-Bisphosphatase Inhibitor and Metformin in the Female ZDF Rat", Abstracts of the 41 st Annual Meeting of The European Association for the Study of Diabetes, Athens, Greece <i>Diabetologia</i> 48(1): A278 Abstract No. 765 Springer-Verlag (August 2005).	
	R34	VAN POELJE, P.D. <i>et al.</i> , "Inhibition of Fructose 1,6-Bisphosphatase Reduces Excessive Endogenous Glucose Production and Attenuates Hyperglycemia in Zucker Diabetic Fatty Rats" <i>Diabetes</i> 55: 1747-1754, American Diabetes Association (June 2006).	
	R35	VAN POELJE, P.D. <i>et al.</i> , "MB06322 (CS-917) Lowers Blood Glucose in Rodents by Inhibiting Both Hepatic and Renal Gluconeogenesis" <i>DIAEAZ</i> 55(1): A137, Journal of the American Diabetes Association Abstract No. 575-P, American Diabetes Association (June 2006).	
	R36	VAN POELJE, P.D. <i>et al.</i> , "Fructose 1,6-Bisphosphatase Inhibition Enhances the Antidiabetic Activity of Insulin Sensitizers in the ZDF Rat" <i>DIAEAZ</i> 52(2): A366, Journal of the American Diabetes Association Abstract No. 1524-P, American Diabetes Association (June 2004).	
	R37	VAN POELJE, P.D. "MB06322, a Potent Inhibitor of Gluconeogenesis, Attenuates Hyperglycemia without Causing Weight Gain or Hypoglycemia in Female Zucker Diabetic Fatty Rats" <i>DIAEAZ</i> 54(1): A124, Journal of the American Diabetes Association Abstract No. 503-P, American Diabetes Association (June 2005).	
	R38	WALKER, J. <i>et al.</i> , "Safety and Tolerability of Single Doses of CS-917, a Novel Gluconeogenesis Inhibitor, in Normal Male Volunteers" <i>DIAEAZ</i> 55(1): A463, Journal of the American Diabetes Association Abstract No. 2002-PO, American Diabetes Association (June 2006).	
PL	R39	WALKER, J. <i>et al.</i> , "Safety, Tolerability and Pharmacodynamics of Multiple Doses of CS-917 in Normal Volunteers" <i>DIAEAZ</i> 55(1): A464, Journal of the American Diabetes Association Abstract No. 2003-PO, American Diabetes Association (June 2006).	

Examiner Signature	<i>Patricia L...</i>	Date Considered	7-22-07
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Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)			Complete if Known		
			Application Number	10/780,948	
			Filing Date	February 17, 2004	
			First Named Inventor	Mark D. Erion	
			Group Art Unit	1614	
			Examiner Name		
Sheet	6	of	6	Attorney Docket Number	MET-016XDT

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PL	R40	YOSHIDA, T. <i>et al.</i> , "Comparison of Acute and Chronic Glucose-Lowering Effect of CS-917, a Fructose 1,6-Bisphosphatase (FBPase) Inhibitor, and Metformin in Rat Models of Type 2 Diabetes" poster presented at The American Diabetes Association 66 th Scientific Session, Washington, DC (June 2006).	
PL	R41	YOSHIDA, T. <i>et al.</i> , "CS-917, a Fructose 1,6-Bisphosphatase Inhibitor, Has Glucose-Lowering Effects in Cynomolgus Monkeys and Improves Postprandial Hyperglycemia in Goto-Kakizaki (GK) Rats" <i>DIAEAZ</i> 54(1): A116, Journal of the American Diabetes Association Abstract No. 472-P, American Diabetes Association (June 2005).	
	R42		
	R43		
	R44		
	R45		
	R46		
	R47		
	R48		
	R49		

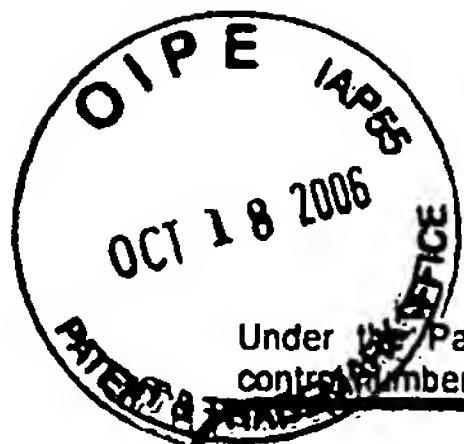
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Complete if Known

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First Named Inventor	Mark D. Erion
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Attorney Docket Number	MET-016XDT

Sheet 1 of 1

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R	R1	VAN POELJE, PAUL D. <i>et al.</i> "Combination Therapy with Pioglitazone and a Fructose-1,6-bisphosphatase Inhibitor (MB06322; CS-917) Improves Glycaemic Control and Lactate Homeostasis in Male Zucker Diabetic Fatty (ZDF) Rates" poster presented at the European Association for the Study of Diabetes (EASD), Copenhagen, Denmark, September 14-17, 2006.	
	R2		
	R3		
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